90-1583

Supreme Court, U.S.
FILED
APR 15 1991
OFFICE OF THE CLERK

No.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

LEONARD S. DINO,
Petitioner,

VS.

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF THE UNITED STATES

DANIEL V. O'BRIEN
STEPHEN H. GILMORE
1921 So. Brentwood Blvd.
St. Louis, Missouri 63114
(314) 961-4365

Attorneys for Petitioner

St. Louis Law Printing, Inc. 13307 Manchester Rd. St. Louis, MO 63131 314-231-4477

QUESTIONS PRESENTED

1. Did the Trial Court err in permitting the submission of the Mail Fraud counts of the Indictment to the jury in opposition to *McNally vs. United States*, 483 U.S. 350?

2. Did the Trial Court err in permitting the submission of the issue of adulteration of a sample drug to the jury without sufficient factual evidence for any expert opinion in violation of Rule 705, Federal Rules of Evidence?

3. Did the Trial Court err in permitting the issue of misbranding of sample drugs to be submitted to the jury?

PARTIES IN THE COURT BELOW

The Peitioner, Leonard S. Dino, was found guilty of three counts of Mail Fraud in violation of 18 U.S.C., Section 2, and 1341; one count of receiving and delivering adulterated and misbranded drugs in violation of 21 U.S.C., Section 331(c) and 333(b); and conspiracy to commit these offenses in violation of 18 U.S.C., Section 371, in the United States District Court for the Eastern District of Missouri.

The United States of America is the Respondent.

TABLE OF CONTENTS

	Page
Questions Presented	i
Parties in the Court Below	ii
Table of Contents	iii
Table of Authorities	v
Jurisdiction	1
Constitutional Provision and Statutes Involved	ii
Statement of the Case	2
Reasons for Granting the Writ	6
I. This case presents questions concerning whether it was the intent of the mail fraud statute to control the purchase and sale of sample drugs when no specific criminal statute was passed until after the date of the transaction on which petitioner was indicted.	6
II. This case presents questions concerning the lack of sufficient factual evidence for an expert opinion as to the adulteration of drugs.	8
III. This case presents questions concerning the plain error committed by the trial court in permitting the issue of misbranding of sample drugs to be submitted to the Jury.	10
Conclusion	11

Appendix A: Statutory provisions and Federal Sentencing Guideline Sections A-1

Appendix B: Indictment in Trial Court A-10

Appendix C: Transcript of Examination A-17

Appendix D: Eighth Circuit Court of Appeals Opinion A-36

Appendix E: Order Denying Petition for Rehearing with Suggestion for Rehearing en banc A-44

TABLE OF AUTHORITIES

Page

Cases:

McNally v. United States, 483 U.S. 350; 97L. Ed. 2d 292, 107 S. Ct. 2875 6,7

United States v. Lew, 875 F. 2d 219 (9th Cir. 1989) 7

United States v. Zauber, 857 F. 2d 137 (3rd Cir. 1988) 7

Daniels v. Matthews, 567 F. 2d 845 (8th Cir.) 9

United States v. Various Articles of Drugs, 332 F. 2d 286 287-288 (3d Cir. 1964) 10

United States v. Various Articles of Drugs Consisting of Unknown Quantities of Prescription Drugs, 207 F. Supp. 480, 482-483 (S.D.N.Y. 1962) 10

United States v. Articles of Drugs, 625 F. 2d 665, 673 (5th Cir. 1980) 10

United States v. Evers, 643 F. 2d 1043, 1052 (5th Cir. 1980) 11

Davis v. Wyeth Laboratories, Inc., 399 F. 2d 121, 130 (9th Cir. 1968) 11

Statutes:

18 United States Code, Section 2 2

18 United States Code, Section 1341 2

18 United States Code, Section371 2

Federal Rules of Evidence, Section 705 9

No.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

LEONARD S. DINO,
Petitioner,

VS.

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF THE UNITED STATES

The Petitioner, Leonard S. Dino, respectfully prays that a Writ of Certiorari issue to review the judgment of United States Court of Appeals for the Eighth Circuit entered in this proceeding on November 14, 1990; and whose Petition for Rehearing was denied on February 11, 1991.

JURISDICTION

The Petition for Certiorari is filed within sixty (60) days of that date. Review is sought pursuant to 28 U.S.C. § 1254.

CITATIONS TO OPINION BELOW

The United States Court of Appeals Opinion is cited at 919 F. 2d 72. Pages, A to A-36.

STATEMENT OF THE CASE

Leonard Dino, Appellant/Defendant (hereinafter Petitioner) was indicted on five counts of Mail Fraud in violation of 18 U.S.C. 2, and 1341; Receiving and Delivering Adulterated and Misbranded Drugs in violation of 21 U.S.C. 331(c), and 331(b), and Conspiracy to commit these offenses in violation of 18 U.S.C. 371. (App. A-7). Dino was fined $10,000.00 on each of Counts I and II, sentenced to concurrent terms of twelve months imprisonment, with ninety (90) days to be served on work release, and the remaining nine months suspended. The District Court suspended imposition of sentence on one remaining mail fraud count, the conspiracy count, and the receiving and delivering adulterated and misbranded drugs.

On appeal it was admitted that Petitioner purchased sample drugs from salesmen of drug manufacturers, and used the samples to fill prescriptions ultimately purchased by customers.Since there was no statute forbidding the sale of drug samples (as found by the Eighth Circuit), he, Dino, was charged with Mail Fraud, Conspiracy to Defraud, and Misbranding and Adulteration, which convictions were affirmed.

The following facts are which led to the conviction of the Petitioner on the various counts.

MAIL FRAUD

The indictment regarding the Mail Fraud counts all have the following common allegation:

"Leonard Dino. . . . unlawfully, willfully, and knowingly devised and intended to devise a scheme and artifice to defraud various drug manufacturers and the drug consuming public, and to obtain money and property by means of false and fraudulent pretenses, representations, and promises. . ."

The Eighth Circuit then found that the selling of sample drugs to consumers deprived the manufacturer of the profit it would get if the products were sold through normal channels, and that the customers (the public) would not be getting basic safeguards which drug companies take pains to provide. The Court then concludes that such conduct is a fraudulent misrepresentation for profit.

Dino's position was, as stated by Government Witness, John Rogeberg, Director of Security for Carter-Wallace, Inc., who stated, as did Defendant Dino, that there was no federal legislation regarding drug diversion and samples until July 20, 1988, after the date of the alleged offenses occurring in this case.

Rogeberg also stated that the sale of sample drugs was widespread enough to cause concern. His only answer as to what occurred regarding his company is that the pharmaceutical samples "were only to be given physicians at their request." No other evidence was submitted in what way the drug manufacturers would be deprived of any profits or monetary gain regarding such a practice.

As to the public losing anything of value or of a proprietary interest, the only testimony as to what occurred when such drugs were sold was by Petitioner Dino, who explained that the use of sample drugs were that such drugs would be the same quality, but with different type distribution, and that the bringing in of the samples caused the cost to be lowered to Dino, who in return reduced the cost to the public service (App. 354-355 TR3-54-55). A-10.

The minimal amount of sample drugs in relation to the overall operation of the company was reflected by the undisputed testimony of Julia Hogan, the Office Manager and Administrative Assistant of Leehar Distributors, Dino's company, who helped to prepare and testify to Defendant's Exhibit L. which reflected that the total amounts of purchases being at either just less or just more than one percent of the total purchases of the organization. (Tr. 2-164-165 A-24-25.)

ADULTERATION AND MISBRANDING

Government Witness, Kenneth Blessel, Director of Quality Control of the pharmaceutical firm of Carter-Wallace, Inc., testified as to the manufacturing and placing in containers for dispensation the cough medicine known as Tussi-Organadin, and Tussi-Organadin, DM, which containers he selected for Tussi cough syrup.

Blessel was then shown various containers, being Government's Exhibits 8A, B, C & D, and testified that no studies had ever been done on these particular containers which were found at Petitioner's drugstore location. He was asked various technical questions concerning the exhibits, and then gave the opinion on direct examination of certain conditions such as if paneling had occurred, it could possibly cause adulteration. On cross examination he stated he never examined any of the containers (Government's Exhibit 8 Series), and was basing his opinion on general knowledge and not on the exhibits in particular. He additionally said without stability studies on the containers (jugs) used in Defendant's drug store, he couldn't give an opinion as to the life expectancy of the particular container without other studies. App. (TR 2-28-34) A-17-23.

Petitioner's expert, David William Levinson, Chemical Engineer, employed by Triadyne-Tassink Associates (engineering consulting firm), examined the jugs. He stated that the damage

on the bottles in question was from the outside inward. He stated that the containers used by Dino were as opposed to those used by the manufacturer of Tussi, and his examination revealed there was no leaking, no paneling, and that the liquid inside (cough medicine) the containers would not be adulterated because there was no such leaking and/or paneling. App. (TR 3-21-26) A- 27-32.

MISBRANDING

Regarding the misbranding of drugs, the matter will be addressed in the portion of this Petition entitled Reasons for Granting The Writ, infra.

CONSPIRACY

The Government failed to present sufficient submissible evidence to prove the substantive offenses of Mail Fraud and causing receipt in interstate commerce of adulterated and misbranded drugs. Without sufficient proof of the substantive offenses, the conspiracy convection cannot stand.

REASONS FOR GRANTING THE WRIT

THIS CASE PRESENTS QUESTIONS CONCERNING WHETHER IT WAS THE INTENT OF THE MAIL FRAUD STATUTE TO CONTROL THE PURCHASE AND SALE OF SAMPLE DRUGS WHEN NO SPECIFIC CRIMINAL STATUTE WAS PASSED UNTIL AFTER THE DATE OF THE TRANSACTION ON WHICH PETITIONER WAS INDICTED.

Upon reviewing the opinion of the Eighth Circuit, it would appear that the term "profit" as being synonymous with that of proprietary interest. It would appear that this particular terminology was used in the instant case to satisfy the standards as set forth by the Supreme Court in *McNally v. United States*, 483 U.S. 350.

As this Court is aware, *McNally* held that insofar as the sparse legislative history of the act, it indicates that the original impetus behind the Mail Fraud Statute was to protect the people from schemes to deprive them of their money or property. Citing *Hammerschmidt v. United States*, in *McNally*, the Court further found that the words "defraud" commonly referred to "wrongdoing one in his property rights by dishonest methods or schemes," and usually signified the deprivation of something of value by trick, deceit, chicane, or overreaching. The Court further stated that when there are two rational readings of a criminal statute, the harsher is to only be read when Congress has spoken in clear and definite language. Furthermore, the Court held that there be no

constructive offense, and before one can be punished, it must be shown that the case is plainly within the statute.

Regarding the Mail Fraud Statute in the instant case, the Eighth Circuit held that since there was no legislation in effect until 1988, that the indictment was that of Mail Fraud. It would appear to be that the "profit" referred to by the Eighth Circuit was minuscule. As stated, the percentage was either just less than one or over one percent of the total purchase of the drugs involved in the operation of the pharmaceutical business by Leonard Dino.

Also, it is suggested that the legislation passed subsequently in the year 1988, known as the "Dingle" act, 21 U.S.C. 353, (A-2), states nothing as to the financial protection of either the manufacturers or the ultimate consumers of sample drugs. What is before the Court on the trial of Petitioner, was not the violation of any law pertaining to the purchase and/or sale of drug samples, but merely a policy of a drug manufacturer, Carter-Wallace, Inc., that samples were not for resale.

It is suggested that the Eighth Circuit by inserting the word "profit" in its Opinion, attempts to tailor a non-criminal violation of the purchase and sale of drug samples into a Mail Fraud offense in direct opposition to the reasoning set forth in *McNally vs. United States*. Even with the subsequent legislation, it was basically for the control of such drugs, as to reasons other than for law to protect the defrauding of drug manufacturers and the consuming public. Additionally, the profit, if any, that was derived from this operation was so infinitesimal that it is obvious from the inception of any purchasing and/or selling of such drugs, it was not with the idea of defrauding either the manufacturer and/or the consuming public.

It is submitted that no evidence was adduced to establish that the manufacturer or the customers were defrauded, or that the manufacturer or the public was deceived and, hence, this case is

indistinguishable from *McNally*. See *United States v. Lew*, 875 F.2d 219, and *United States v. Zauber*, 857 F. 2 d 137.

THIS CASE PRESENTS QUESTIONS CONCERNING THE LACK OF SUFFICIENT FACTUAL EVIDENCE FOR AN EXPERT OPINION AS TO THE ADULTERATION OF DRUGS.

The Government witness as to adulteration was Ken Blessel, Director of Quality Control of the drug manufacturer, Carter-Wallace. After being qualified as an expert, he advised that his employers made a series of cough medicines known as the "Tussi Series", one being Tussi-Organadin, and the other was Tussi-Organadin, DM. It was his input that went into the design of the jug-shaped container that Tussi would use for purposes of distribution. He then testified as to the containers being marked Government's Exhibits 8 A through D, which containers were taken from the store of Petitioner. He mentioned that he never did any type of study on these particular containers, but said he thought the wall thickness could probably allow for the container to collapse. He then qualified this by saying that it could not be determined to be so by just sitting on the stand and talking to the prosecutor. He said in his opinion that the containers in the Exhibit 8 Series appeared to collapse inwardly, and excessively. He further said that there would appear to be a type of chemical reaction which is known as paneling, that is caused on a plastic container, and that what he saw was a deformation response to that stress as determined by a number of different things that could happen. He mentioned that one thing is what is known as leaching of the plasticizers out of the walls of the container causing them to collapse inward. In response to a hypothetical question of the prosecutor, if the Tussi cough medicine was placed into the container, such as in the Exhibit 8 Series, that as a result of the foregoing reactions on the container, there could be adulteration. (App 2-28-34 A- 17-23.) However, upon cross

examination he had indicated he did not test any of the containers and that the opinion he gave in regard to them was on general knowledge and not on specific testing of the exhibits in evidence. (App. 2-28-34 A -17-23.) The witness assumed as a fact that paneling existed with no factual basis other than this assumption.

It is suggested that this particular type of testimony would not establish adulteration of the cough medicine product since there was insufficient factual information for a hypothetical question for it to be submitted to a jury.

It is obvious that the facts submitted under Rule 705 Federal Rules of Evidence allow counsel to make use of a hypothetical question. However, if a hypothetical question is used, the question must reveal the factual premise which is basis for the expert's opinion. *Daniels v. Matthews,* 567 F. 2d 845, is authority as to pre-federal rules which held that it is proper to phrase a hypothetical question by a clear reference to certain specified testimony, or by enumeration by the questioner of certain basic facts adduced in other testimony, for which there is *sufficient* (emphasis ours) evidence to support a jury finding that these facts exist.

In the case at bar, there was insufficient evidence adduced to permit Plaintiff witness, Blessel, to give an expert opinion, since he was not denied the opportunity to examine the containers (jugs), but apparently did not do so. By looking at these containers without maintaining what was called the stability study test, he gives the opinion that there could be this paneling which would result in possible leaching and, accordingly, could lead into adulteration of the products (cough medicine).

Yet, on cross examination, he stated he never did conduct any tests on the bottles in question and, in effect, assumed into evidence that paneling occurred.

It would appear that the testimony of the witness violated the basic proposition that the opinion must be premised on some factual information, which in this case would have necessitated at least the examining of the Series 8 containers admitted into evidence against Petitioner. The witnesses' testimony was giving an opinion to the ultimate fact of adulteration of which Petitioner was found guilty.

THIS CASE PRESENTS QUESTIONS CONCERNING THE PLAIN ERROR COMMITTED BY THE TRIAL COURT IN PERMITTING THE ISSUE OF MISBRANDING OF SAMPLE DRUGS TO BE SUBMITTED TO THE JURY FOR ITS DELIBERATION.

A review of the evidence makes it equally clear that the government failed to prove that the drugs at issue were misbranded. Marketing of sample drugs is not *per se* misbranding. *See United States v. Various Articles of Drugs*, 332 F.2d 286, 287-288 (3d Cir. 1964); *United States v. Various Articles of Drugs Consisting of Unknown quantities of Prescription Drugs*, 207 F. Supp. 480, 482-483 (S.D.N.Y. 1962). Removing the labeling indicating that a prescription drug is a "Sample" or other such labeling and repacking such samples for sale to a retail pharmacy is not misbranding under 21 U.S.C. Section 352 (a) as it does not render the labeling false or misleading in any particular, *Id.*, nor is it misbranding under subsection (b). The labeling of the items purchased for Council Plaza were not false and misleading, as they indicated the name of the drug and the quantity.

The government also contended that the items were misbranded pursuant to 21 U.S.C. Section 352 (f) because the labels did not contain "adequate directions for use" and "adequate warnings." Such requirements are unnecessary for prescription drugs, and all of the drugs at issue were prescription. *See United States v. Articles of Drug*, 625 F.2d 665, 673 (5th Cir. 1980).

This exemption to subsection (f) for prescription drugs is based on the fact that the physician is responsible for making sure that the appropriate warnings to the patient appear on the label based on his professional judgment. Thus, the distributor or manufacturer of the drug must provide adequate information to the physician, but such information need not be given to the patient/consumer. *United States v. Evers,* 643 F. 2d 1043, 1052 (5th Cir. 1981). Adequate directions for use and adequate warnings to the ultimate consumer/patient are not required on prescription drugs because the choice involved is essentially a medical one involving an assessment of medical risks in light of the doctor's knowledge of his patient's needs. *Davis v. Wyeth Laboratories, Inc.,* 399 F.2d 121, 130 (9th Cir. 1968). Since all the drugs at issue were prescription drugs, failure to include directions for use and warnings to the ultimate consumer does not constitute misbranding thereof.)

CONCLUSION

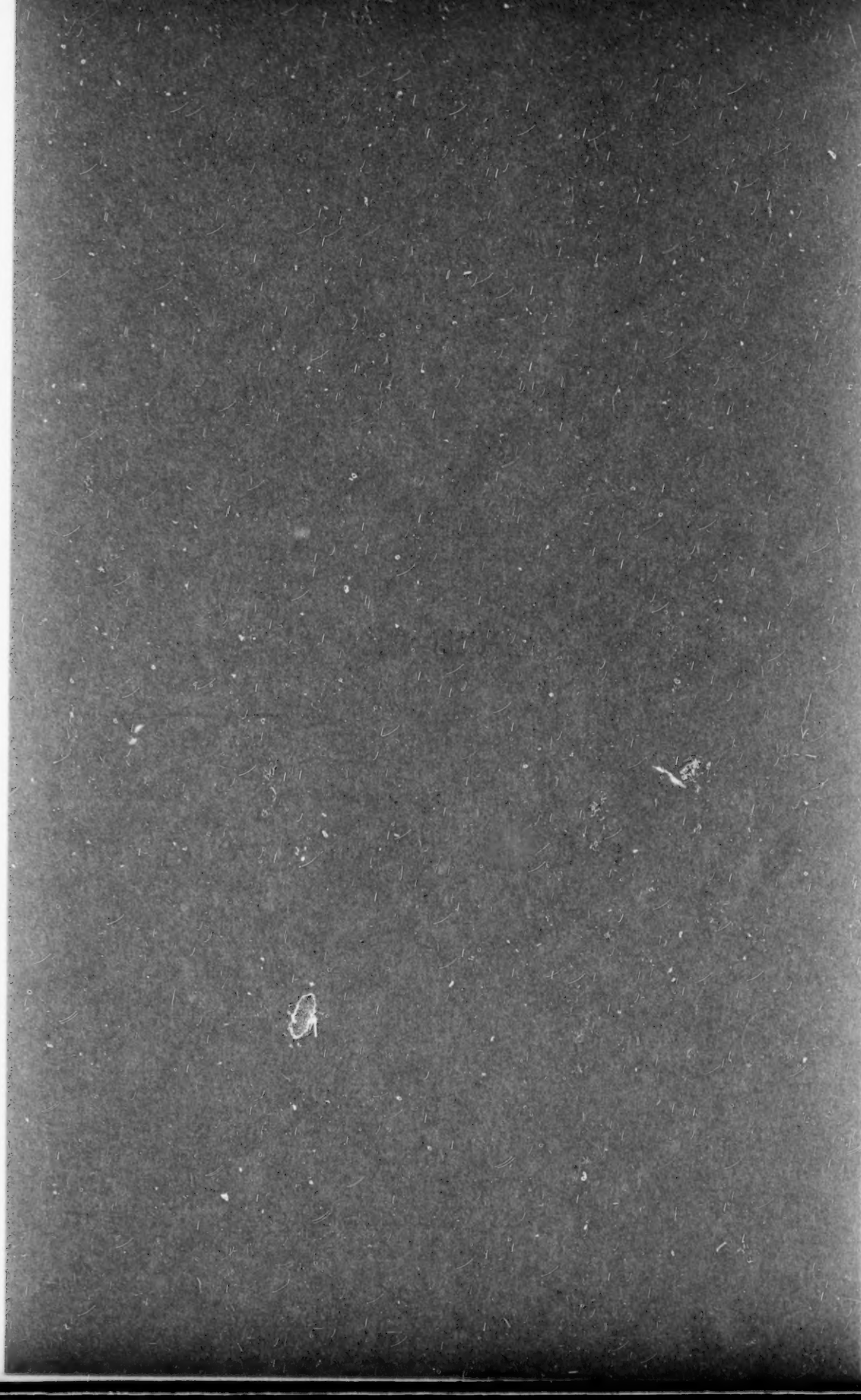
For the foregoing reasons a Writ of Certiorari should be issued to review the judgment of the United States Court of Appeals.

Respectfully submitted,

DANIEL V. O'BRIEN and
STEPHEN H. GILMORE
1921 South Brentwood Boulevard
St. Louis, Missouri 63144
(314) 961-4365

Attorneys for Petitioner

APPENDIX



Appendix A

18 U.S.C. § 2. **Principals**

(2) Whoever commits an offense against the United States or aid, abets, counsels, commands, induces or procures its commission, is punishable as a principal.

(b) Whoever willfully causes an act to be done which if directly performed by him or another would be an offense against the United States, is punishable as a principal.

June 25, 1948, c. 645, 62 Stat. 684; Oct 31, 1951, c. 655, § 17b, 65 Stat. 717.

18 U.S.C. § 1341. **Frauds and swindles**

Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulence pretenses, representation, or promises, or to sell, dispose of , loan, exchange, alter, give away, distribute, supply, or furnish or procure for unlawful use any counterfeit or spurious coin, obligation, security or other article, or anything represented to be or intimated or held out to be such counterfeit or spurious article, for the purpose of executing such scheme or artifice or attempting so to do, places in any post office or authorized depository for mail matter, any matter or thing whatever to be sent or delivered by the Postal Service, or takes or receives therefrom, any such matter or thing, or knowingly causes to be delivered by mail according to the direction thereon or at the place at which it is directed to be delivered by the person to whom it is addressed, any such matter or thing, shall be fined not more than $1,000 or imprisoned not fore than five years, or both.

(June 25, 1948, c. 645, 62 Stat 763; May 24, 1949, c. 139, § 34, 63 Stat. 94; Aug 12, 1970, Pub.L. 91-375, § 6(j)(11), 84 Stat. 778.)

18 U.S.C. § 371. **Conspiracy to commit offense or to defraud United States**

If two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons to any act to effect the object of the conspiracy, each shall be fined not more than $10,000 or imprisoned not more than five years, or both.

If, however, the offense, the commission of which is the object of the conspiracy, is a misdemeanor only, the punishment for such conspiracy shall not exceed the maximum punishment provided for such misdemeanor. June 25, 1948, c. 645, 62 Stat. 701.

21 USCS § 353. **Exemptions in case of drugs and devices**

(a), (b) [Unchanged]

(c) **Sales restrictions.** (1) No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. For purposes of this paragraph and subsection (d), the term "drug sample" means a unit of a drug, subject to subsection (b), which is not intended to be sold and is intended to promote the sale of the drug. Nothing in this paragraph shall subject an officer or executive of a drug manufacturer or distributor to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade in violation of this paragraph by other employees of the manufacturer or distributor.

(2) No person may sell, purchase, or trade, offer to sell, purchase, or trade, or counterfeit any coupon. For purposes of this paragraph, the term "coupon" means a form which may be redeemed, at no cost or at a reduced cost, for a drug which is prescribed in accordance with section 503(b) [subsec. (a) of this section].

(3)(A) No person may sell, purchase, or trade, or offer to sell, purchase, or trade, any drug—

(i) which is subject to subsection (b) and

(ii)(I) which was purchased by a public or private hospital or other health care entity or

(II) which was donated or supplied at a reduced price to a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 [26 USCS § 501(c)(3)].

(B) Subparagraph (A) does not apply to

(i) the purchase or other acquisition by a hospital or other health care entity which is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities which are members of such organization,

(ii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade of a drug by an organization described in subparagraph (A)(ii)(II) to a nonprofit affiliate of the organization to the extent otherwise permitted by law,

(iii) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities which are under common control,

(iv) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, or

(v) a sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription executed in accordance with section 503(b) [subsec. (b) of this section].

For purposes of this paragraph, the term "entity" does not include a wholesale distributor of drugs or a retail pharmacy licensed

under State law and the term "emergency medical reasons" includes transfers of drug between health care entities or from a health care entity to a retail pharmacy undertaken to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules.

(d) **Distribution of drug samples.** (1) Except as provided in paragraphs (2) and (3), no representative of a drug manufacturer of distributor may distribute any drug sample.

(2)(A) The manufacturer or distributor of a drug subject to subsection (b) may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities. Such a distribution of drug samples may only me made—

(i) in response to a written request for drug samples made on a form which meets the requirements of subparagraph (B), and

(ii) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or distributor.

(B) A written request for a drug sample required by subparagraph (A)(i) shall contain—

(i) the name, address, professional designation, and signature of the practitioner making the request,

(ii) the identity of the drug sample requested and the quantity requested,

(iii) the name of the manufacturer of the drug sample requested, and

(iv) the date of the request.

(C) Each drug manufacturer or distributor which makes distributions by mail or common carrier under this paragraph shall maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and shall maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. forms, receipts, and records required to be maintained under this subparagraph shall be made available by the drug manufacturer or distributor to Federal and State officials engaged in the regulation of drugs and in the enforcement of laws applicable to drugs.

(3) The manufacturer or distributor of a drug subject to subsection (b) may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or distributor makes the distributions in accordance with subparagraph (A) and carrier out the activities described in subparagraphs (B) through (F) as follows:

(A) Drug samples may only be distributed—

(i) to practitioners licensed to prescribe such drugs if they make a written request for the drug samples, or

(ii) at the written request of such a licensed practitioner, to pharmacies of hospitals or other health care entities.

A written request for drug samples shall be made on a form which contains practitioner's name, address, and professional designation, the identity of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or distributor of the drug sample, the date of the request and signature of the practitioner making the request.

(B) Drug manufacturers or distributors shall store drug samples under conditions that will maintain their stability, integrity, and effectiveness and will assure that the drug samples will be free of contamination, deterioration, and adulteration.

(C) Drug manufacturers or distributors shall conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or distributor. Drug manufacturers or distributors shall maintain lists of the names and address of each of their representatives who distribute drug samples and of the sites where drug samples are stored. Drug manufacturers or distributors shall maintain records for at least 3 years of all drug samples distributed, destroyed, or returned to the manufacturer or distributor, of all inventories maintained under this subparagraph, of all thefts or significant losses of drug samples, and of all requests made under subparagraph (A) for drug samples. Records and lists maintained under this subparagraph shall be made available by the drug manufacturer or distributor to the Secretary upon request.

(d) Drug manufacturers or distributors shall notify the Secretary of any significant loss of drug samples and any known theft of drug samples.

(E) Drug manufacturers or distributors shall report to the Secretary any conviction of their representatives for violations of section 503(c)(1) [subsec. (a)(1) of this section] or a State law because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(F) Drug manufacturers or distributors shall provide to the Secretary the name and telephone number of the individual responsible for responding to a request for information respecting drug samples.

(e) **Wholesale distribution [Caution: see the Other provision note for effective date]**. (1) Each person who is engaged in the wholesale distribution of drugs subject to subsection (b) and who is not an authorized distributor of record of such drugs shall provide to each wholesale distributor of such drugs a statement identifying each sale of the drug (including the date of the sale)

before the sale to such wholesale distributor. Each manufacturer shall maintain at its corporate offices a current list of such authorized distributors.

(2)(A) No person may engage in the wholesale distribution in interstate commerce of drugs subject to subsection (b) in a State unless such person is licensed by the State in accordance with guidelines issued under subparagraph (B).

(B) The Secretary shall by regulation issue guidelines establishing minimum standards, terms, and conditions for the licensing of persons to make wholesale distributions in interstate commerce of drugs subject to subsection (b). Such guidelines shall prescribe requirements for the storage and handling of such drugs and the establishment and maintenance of records of the distributions of such drugs.

(3) For the purposes of this subsection—

(A) the term "authorized distributors of record" means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products, and

(B) the term "wholesale distribution" means distribution of drugs subject to subsection

(b) to other than the consumer or patient but does not include intracompany sales and does not include distribution of drugs described in subsection (c)(3)(B).

[(f)](c) **Veterinary prescription drugs**. (1)(A) A drug intended for use by animals other than man which—

(i) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for animal use except under the professional supervision of a licensed veterinarian, or

(ii) is limited by an approved application under subsection (b) of section 512 [21 USCS § 306B(b)] to use under the professional supervision of a licensed veterinarian, shall be dispensed only by or upon the lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice.

(B) For purposes of subparagraph (A), an order is lawful if the order—

(i) is a prescription or other order authorized by law,

Iii) is, if an oral order, promptly reduced to writing by the person lawfully filling the order, and filed by that person, and

(iii) is refilled only if authorized in the original order or in a subsequent oral order promptly reduced to writing by the person lawfully filling the order, and filed by that person.

(C) The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug when dispensed in accordance with paragraph (1) of this subsection—

(A) shall be exempt from the requirements of section 502 [21 USCS § 352], except subsections (a), (g), (h), (i)(2), (i)(3), and (p) of such section, and

(B) shall be exempt from the packaging requirements of subsections (g), (h), and (p) of such section, if—

(i) when dispensed by a licensed veterinarian, the drug bears a label containing the name and address of the practitioner and any directions for use and cautionary statements specified by the practitioner, or

(ii) when dispensed by filling the lawful order of a licensed veterinarian, the drug bears a label containing the name and

address of the dispenser, the serial number and date of the order or of its filling, the name of the licensed veterinarian, and the directions for use and cautionary statements, if any, contained in such order.

The preceding sentence shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail.

(3) The Secretary may by regulation exempt drugs for animals other than man subject to section 512 [21 USCS § 360b] from the requirements of paragraph (1) when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal lay restricts this drug to use by or on the order of a licensed veterinarian.". A drug to which paragraph (1) does not apply shall be deemed to be misbranded if any any time prior to dispensing its label bears the statement specified in the preceding sentence.

(As amended April 22, 1988, P. O. 100-293, §§ 4-6, 102 Stat. 96-98; Nov. 16, 1988 P. L. 100-670, Title I, § 105, 102 Stat. 3983).

APPENDIX B

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

No.

UNITED STATES OF AMERICA,
Plaintiff,

v.

LEONARD S. DINO and JOSEPH GRECO,
Defendants.

COUNT I

The Grand Jury charges:

1. That at times relevant to this indictment, the defendant, LEONARD S. DINO, was the President and Chief Executive Officer of Leehar Distributors, Inc., a Missouri Corporation which owned and operated Council Plaza Pharmacy, both of which are located and do business at 232 South Grand Avenue, St. Louis, Missouri.

That LEONARD S. DINO also owns and operates St. Joseph's Professional Pharmacy in Alton, Illinois.

That LEONARD S. DINO and JOSEPH GRECO are licensed pharmacists in the State of Missouri.

That JOSEPH GRECO was and is a manager who works for LEONARD S. DINO and Leehar Distributors Inc., d.b.a. Council Plaza Pharmacy.

That Leehar Distributors Inc., d.b.a. Council Plaza Pharmacy, and St. Joseph's Professional Pharmacy, sold drugs to the drug consuming public in the State of Missouri and the State of Illinois.

2. Between on or about March 8, 1982, through on or about September 30, 1986, in the Eastern District of Missouri and elsewhere, the defendants,

LEONARD S. DINO and JOSEPH GRECO,

aided and abetted by others, unlawfully, willfully and knowingly devised and intended to devise a scheme and artifice to defraud various drug manufacturers and the drug consuming public and to obtain money and property by means of false and fraudulent pretenses, representations and promises.

3. The said scheme and artifice to defraud devised and intended to be devised by the defendants was in substance as follows:

A. That the defendants, LEONARD S. DINO and JOSEPH GRECO, and others, acting together, solicited and paid sales representatives of various drug manufacturers to deliver to the defendants "sample" or "not for resale" drugs which the sales representatives did not personally own and which said drugs the sales representatives had no authorization or permission to deliver;

B. That the defendants, LEONARD S. DINO and JOSEPH GRECO, and others, acting together, removed or caused the removal, under less than good manufacturing practice, of the original packaging and labeling of these drugs and placed the now adulterated drugs in plastic baggies, plastic gallon jugs or other unauthorized containers without accurate and verifiable lot numbers, expiration dates, and other required data;

C. That the defendants, LEONARD S. DINO and JOSEPH GRECO, and others acting together, did sell or cause to be sold these adulterated and misbranded drugs and other fraudulently obtained drugs to the drug consuming

public of Council Plaza Pharmacy and other pharmacies owned and/or operated by the defendants.

D. That the defendants, LEONARD S. DINO and JOSEPH GRECO, did compromise or cause to be compromised the product integrity of these drugs by reselling drugs which could not be recalled in an emergency and whose potency and purity could no longer be assured.

4. It was part of the scheme and artifice to defraud that the defendants made the following false and fraudulent representations, promises and pretenses:

1. The defendants, JOSEPH GRECO and LEONARD S. DINO, operating and doing business as Council Plaza Pharmacy, represented that the drugs they sold to the drug consuming public were pure, potent and maintained in sanitary and proper conditions, when in truth and fact, as the defendants well knew, the drugs were intended to be used as samples and the storage conditions and lot numbers were, for the most part, unknown and the expiration dates were unknown or expired.

5. That on or about July 8, 1983, in the Eastern District of Missouri, the defendants LEONARD S. DINO, JOSEPH GRECO, and others, for the purpose of executing the aforedescribed scheme and artifice to defraud and to obtain money by means of false and fraudulent pretenses and representations and attempting to do so, did knowingly and willfully cause to be delivered by mail according to the directions thereon, an envelope containing a check for delivery to Dick Meyers, 1774 Kimkirk, St. Louis, Mo 63103, to be sent and delivered by the United States Postal Service.

In violation of Title 18, United States Code, Sections 2 and 1341.

COUNTS II THROUGH V

The Grand Jury further charges that:

1. The allegations contained in Paragraph 1 through 4 of Count I are realleged and incorporated herein by reference.

2. On or about the dates listed below, within the Eastern District of Missouri and elsewhere,

LEONARD S. DINO and JOSEPH GRECO,

the defendants herein, for the purpose of executing the aforesaid scheme and artifice to defraud, and attempting to do so, did knowingly and willfully cause to be placed in an authorized depository for mail matter, to be sent and delivered by the U.S. Postal Service according to the directions thereon, the articles listed below, each such use of the mails being a separate count of this indictment:

Count	Approximate Date of Mailing	Article	Sender	Addressee
II	Sept. 22, 1983	$939.12 check	Leehar Distributors, Inc. 232 S. Grand St. Louis, MO 63103	Dick Meyer 1774 Kimkirk St. Louis, MO 63122
III	August 9, 1986	Order List for Samples	Leehar Distributors, Inc. 232 S. Grand St. Louis, MO 63103	Dick Meyer 1774 Kimkirk St. Louis, MO 63122
V	April 7, 1986	Envelope with Receipt	Robert E. Haller 772 Vanderville Dr. Fenton, MO 63026	Council Plaza Pharm. 232 So. Grand St. Louis, MO 63102

All in violation of Title 18, United States Code, Sections 2 and 1341.

COUNT VI

The Grand Jury further charges:

1. Paragraphs one through four of Count I are realleged and incorporated herein by reference.

2. Between on or about 1977, through on or about September 30, 1986, in the Eastern District of Missouri and elsewhere, the defendants,

LEONARD S. DINO and JOSEPH GRECO

along with others, did knowingly and willfully combine, conspire, confederate and agree with each other to commit certain offenses against the United States, including:

A. With the intent to defraud and mislead, caused the receipt in interstate commerce of adulterated and misbranded drugs, as defined in Title 21, United States Code, Sections 351(a)(2)(A), 351(a)(2)(B), 321(n), and 352(a)(b), and (f), and delivered said drugs for pay, as more fully set forth in Counts One through Five, incorporated by references herein, in violation of Title 21, United States Code, Sections 331(c), and 333(b);

B. Cause the United States mails to be used in the furtherance of a scheme and artifice to defraud drug manufacturers and the drug-consuming public, and to obtain money and property by means of false and fraudulent pretenses, representations and promises, as more fully set forth in Counts One through Five, incorporated by references herein, in violation of Title 18, United States Code, Section 1341 and 2.

3. it was a part of the conspiracy for defendant to purchase sample drugs and other unauthorized diverted drugs which were

originally obtained from drug manufacturers under fraudulent pretenses and thereafter adulterated and misbranded before resale without regard to product potency and purity,.

OVERT ACTS

4. In furtherance of the conspiracy set forth above and to effect the objects thereof, the conspirators in this district and elsewhere committed the following overt acts, among others.

A. The defendants purchased sample drugs and other unauthorized diverted drugs which had been originally obtained from drug manufacturers under false and fraudulent pretenses;

B. The defendants paid sales representatives employed by various drug manufacturers and other to deliver said drugs which they did not personally own;

C. The defendants caused their employees, and others, to remove the drugs from their original packaging and labeling, under less than good manufacturing practice, and to place the now adulterated drugs in plastic baggies or other unauthorized containers, often without accurate and verifiable lot numbers, expiration dates and other required data;

D. The allegations contained in paragraph five of Count I and paragraphs one and two of Counts II trough V are realleged and incorporated by reference.

All in violation of Title 18, United States Code, Section 371.

COUNT VII

The Grand Jury further charges:

Beginning from at least 1977, a specific date unknown to the Grand Jury, through approximately September 30, 1986, in the

Eastern District of Missouri and elsewhere, the defendants,

LEONARD S. DINO and JOSEPH GRECO,

willfully and knowingly, and with intent to defraud and mislead, caused the receipt in interstate commerce of adulterated and misbranded drugs, as defined in Title 21, United States Code, Sections 351(a)(2)(B), 321(N) and 352(A)(B) and (F), and delivered said drugs for pay or otherwise.

APPENDIX C

Steitz/Direct

[2-28]

A. Deteriorated, very badly deteriorated.

Q. Does that show any condition that you're acquainted with?

A. Not in our product. The container appears to have collapsed inward. As best I can tell, it appears to have collapsed inward and is cracked excessively. It's in really bad shape.

Q. Any type of term that you could describe that?

A. It looks like the phenomenon that I have seen before called paneling, and this would be atypical of collapsing, as I said, collapsing inward.

Q. What is paneling, if you could describe that specifically to the jury?

A. Paneling is a stress caused on a plastic container and it's deformation in response to the stress through a number of different things that can happen. For example, you could have differential permeability of water and air through the container and you can actually set up a vacuum inside these containers which will pull the walls in.

The other thing that could happen is you can get leaching of the plasticizers out of the walls of the container and this will also tend to make it collapse inward.

Q. And Doctor, I want you to assume that you Tussi cough syrup was taken out of its original container

with the high density polyplastic and placed into a container like these. What potentially could happen to the product and the jug?

[2-29]

A. Well, first thing is I would have no way of predicating what the shelf life would be. My feeling is that it would be shorter than the container that we have it in. And second of all, the possibility, the strong possibility exists that some of the materials could extract into the product, leach into the product, if you will and actually cause its adulteration.

Q. And how would this leaching occur in relation to these jugs?

A. Being these jugs were designed for aqueous product, our product contains items which make it not behave like a water based product. Specifically our product contains glycerin and propylene glycol which lends a different character, a different polarity, if you will, a different interactiveness to the product.

Q. And what would happen to the potency of the product, assuming your Tussi was placed in a container like that?

A. I would say that *there's a very high likelihood* that it would fall at a more rapid rate simply *because these thinner* walls would be more permeable to air.

Q. Now, let me ask you to *assume that your Tussi was placed in a container like this*.

A. Yes.

Q. *And that paneling occurred*. What would you do if that situation would have arisen?

[2-30]

A. If we had a batch out in the field where the bottles were collapsing, it's very likely that we would recall the entire batch or possibly even multiple bathes.

Q. And how would you recall this, how would you recall the drugs?

A. You would recall it through a unique lot number which is imprinted on the label of every container that's filled out of that particular lot. That lot number allows you to trace the complete manufacturing history of the product.

Q. Now, on the containers that you contain your Tussi in, are there serial numbers and expiration dates?

A. Yes, there are.

Q. Are there also instructions for storage?

A. Indeed, yes, sir.

Q. Can you tell the Court and the jury why it is important to have serial numbers and expiration dates on your Tussi drug or any type of drug?

A. First of all, expiration date. Pharmaceuticals do not maintain their potency forever. The manufacturer does studies to support the fact that the product will retain its potency for the time period listed in the original container and they so label it, and that's to alert the pharmacist to take it out of distribution when it is past that date because we can no longer guarantee its potency.

Q. And how about the serial number or lot number?

A. The lot number is used when for some reason we discover after distribution of the product that something has happened, something has gone wrong and we may have to get it back from the field, and the lot number and the distribution records associated with that lot number is the way that you get that material back, to determine where it went.

Q. Doctor, I'm going to ask you to assume that if your Tussi-Organadin is placed into a container like this and *if paneling had occurred*, what would that indicate to you?

A. The product is interacting in some way, shape or form with the container and very possibly could be adulteration because of its — for example, if the plasticizer for example are leaking into the product, that's an item that does not belong in the product and therefore is an adulterant, pure and simple.

MR. STEITZ: I have nothing further, Judge. Thank you, sir.

THE COURT: Cross examination.

CROSS EXAMINATION

BY MR. MARGULIS:

Q. Mr. Blussel, how many recalls have you had of Tussi-Organadin in the last four years?

A. I don't believe we've had any.

Q. You haven't, have you?

A. Don't believe.

[2-32]

Q. So, there haven't been any recalls of the drug in the last four years, have there?

A. No, sir.

Q. If in fact the lot number and the expiration date were on the shelf by the bottle, then you have a lot number and an expiration date, wouldn't you?

A. It's out of the original container? Are you saying it's out of my original container?

Q. It's up there on the jug or right next to the jug.

A. In the original jug that it came from?

Q. No, sir, in one of these.

A. See, once you take it out of the container that we put it in, that expiration date that we determined with back-up stability studies is no longer valid, so to put that up on the shelf, no, that's not a valid expiration date anymore. The lot number ye, I would agree that's valid.

Q. What about if the lot number and expiration date are kept by computer at Council Plaza Pharmacy as each customer is sold the Tussi-Organadin?

A. Again I'd like to reiterate that the expiration date that we apply only goes on that container, closure system that we have studied in our stability program. It doesn't apply if it's taken out of there and put into some other container. Now, as regard to the lot number,

as long as the lot numbers were not mixed, yes, that would be an adequate number as long as these numbers were not mixed in the container.

[2-33]

Q. And that would be adequate for recall, wouldn't it?

A. That would be adequate for recall, yes.

Q. Did you test these containers?

A. No, sir.

Q. So, the *opinion* you've given us here this morning are based upon your *general knowledge* and not on specific testing of these particular containers?

A. That's right.

Q. True?

A. Yes.

Q. You indicated that you thought the life of these containers was shorter than the high density containers that you all used?

A. That would be my professional judgment, yes.

Q. What about if Council Plaza Pharmacy were buying three to four gallons of Tussi-Organadin a month and selling it that fast?

A. Again, in our gallon container?

Q. No, sir. In these.

A. You know, without the supporting — without the supporting stability studies, I couldn't tell you how long.

Q. That's exactly my point. Without the supporting stability *studies, you can't tell us exactly how long?*

A. *Right.*

[2-34]

Q. And you didn't test these particular jugs?

A. No, sir, I did not.

Q. Does your company furnish any literature to the pharmacists they should maintain?

A. Yes. We tell them how to dispense the material in a prescription.

Q. Do you recall having a telephone conversation with Mr. Dino about that subject last year?

A. No, sir.

Q. You don't remember him calling you and talking to you on September —

A. Me specifically or Carter-Wallace?

Q. Dr. Blussel.

A. No, no, sir, I don't recall such a conversation. I don't believe it ever took place.

Q. On September 2nd, 1988, you don't remember that?

A. Absolutely not. Absolutely not.

MR. MARGULIS: Excuse me just a moment, Judge.

Q. Doctor, more specifically, do you remember talking to Mr. Dino twice on September 2nd, 1988 and once in 1987 wherein he was asking advice about the containers?

A. I don't remember every phone conversation that I ever had, but I certainly have no recollection of this name from before, none whatsoever.

[2-164]

Margulis/Direct

A. Our accounting firm.

Q. Your accounting firm assisted you in preparing it?

A. Yes, sir.

Q. And would you please explain to the Court and to the jury what that is.

A. Yes, sir. The first column — our fiscal year runs from July 1 through June 30th, and in fiscal year 1981-82 total purchases, and total purchases include drugs, over-the-counter items, groceries, tobacco, cigarettes, liquor, supplies, equipment, anything and all that we purchased, and our purchases for 198-82 were $1,089,581. Out of that our drug purchases were $840,463. We had no purchases from Haller, no purchases from Hayes and our purchases from Meyer — this is blurred from here —

Q. Are you having trouble?

A. Yes.

Q. Does that help?

MR. MARGULIS: Judge, can the witness stand here?

THE COURT: Surely.

A. Okay. Our purchases from Meyer's was $2,425.10. The purchases from three salesmen were less than one

percent of our total purchases for 1981-82. They were 22/100 of one percent of our total purchases.

Q. So, let me stop you there. The bottom line is that the total percentage of purchases of sample drugs were less than one percent of your entire purchases, correct?

[2-165]

A. Yes, sir.

Q. And without going through every figure of every year, is that what this chart is meant to depict?

A. Yes, sir.

Q. Well then, without going through all of these figures, Mrs. Hogan, would you just testify as to what percentage the sale of sample drugs made up the entire purchase?

A. In 1982-83 the purchases from the three salesmen were 65/100 of one percent of our total purchases. In 1983-84 the purchases from the three salesmen were 75/100 of one percent of our total purchases. In 1984-85 the purchases from the three salesmen were 1.07 percent of our total purchases. 1985-86 the purchases from the three salesmen were 70/100 of our total purchases.

Q. Did the purchases from these salesmen terminate in the summer of 1986?

A. Yes, sir.

Q. Were you there on the afternoon when Richard Meyer came in and you later learned he was wired?

A. Yes, sir.

Q. Can you explain his behavior on that afternoon?

A. He came in and I believe it was before noontime and he asked for Mr. Dino. I told him that Mr. Dino was not there, he was out in a nursing home, that I had not heard from Mr. Dino and did not know what time he would be back or if he would

[3-21]

Margulis/Direct
Steitz/Cross

Q. If in fact these were in good condition on September 3rd, 1986 and you didn't examine them until approximately a week or ten days ago, could the damage or would the damage likely occurred during that period of time?

A. I think probably it would have.

MR. MARGULIS: I have nothing further, Judge.

THE COURT: Cross examination.

MR. STEITZ: Yes, Judge.

CROSS EXAMINATION

BY MR. STEITZ:

Q. Mr. Levinson, have you testified before, sir?

A. Yes, I have.

Q. And how many times?

A. I have no idea.

Q. Many times?

A. Probably twenty.

Q. In fact, you testified quite often for the Plaintiff's attorney, don't you?

A. No, I testify more often for Defense attorneys.

Q. Insurance companies?

A. Insurance companies.

Q. And you are paid to come here today, weren't you, sir?

A. Yes, sir.

Q. How much were you paid?

A. My laboratory charge is $150 an hour for my services.

[3-21]

Q. And how much were you paid?

A. I have no idea. I haven't submitted a bill yet.

Q. You don't know how many hours it took to do this?

A. Oh, there was some time contributed by one of the organic polymer people at Triadyne and I haven't seen the invoice so I don't know how many hours there are. If you want me to guess at mine, perhaps six to eight.

Q. That's your time?

A. Yes.

Q. Does that include the other people's time?

A. No. There's technician time, there is some electron microscope time.

Q. You don't know how much time was spent then, do you?

A. Well, if you really have to know and if I —

Q. Well, I do. I'm asking you if you can tell me how much time was spent.

A. Well, I've estimated mine. Double it.

Q. Double?

A. Yes.

Q. So, 12 to 16 hours; is that fair?

A. Something like that, I would say, yes.

Q. Now, you said these crackings were caused or were mechanical and it could have been caused by how they were stored?

A. Yes.

[3-22]

Q. They could have been caused by maybe these jugs being in the sun?

A. Yes.

Q. Maybe in the heat?

A. Yes. Not likely heat. Heat would tend to soften the materials, so it wouldn't crack — tends to make it grow.

Q. Would it aid in the cracking if it became soft and then got hard later? Could it?

A. I'm not sure. You mean if it were warmed and softened and then cooled again?

Q. Yes.

A. It might.

Q. And these things, if these things were stored in an evidence room where they were not stacked on top of each other, it was in a relatively calm environment, then their storage in the evidence room wouldn't be a factor in the cracking, would it?

A. It might.

Q. And couldn't the cause of the cracking have come from improper storage maybe at the pharmacy, sir?

A. It could have come from improper storage anywhere.

Q. So it could have been caused by improper storage at a pharmacy, right?

A. I doubt it because I think that if it had been stored improperly where it was being used the leakage that resulted would have certainly alerted someone to change the container.

[3-23

Q. If anyone was paying attention to it, right?

A. Yes.

Q. So it would sit for three to six months, it might start leaking and someone should see it, right?

A. I would think so.

Q. But still the cracking could have been caused by improper storage at a pharmacy, right?

A. Cracking, as I said, could have been caused by improper storage anywhere.

Q. Anywhere. Now, have you done the — let me ask you this: These containers are low density poly-plastic, right?

A. Yes.

Q. Okay. And these were seen to be cracked, right?

A. One of them I think is not.

Q. This one. Well, there's a little crack there.

A. Which one is it? Number three. No. Look at number three. I think number three doesn't have any cracks.

Q. This one has no cracks, right.

A. That's correct.

Q. So, may I guess under your testimony that it was stored properly?

A. I don't associate the cracking necessarily with the storage, although it is indented.

Q. Sir, didn't you say that the cause of the cracking was mechanical and could have been caused by how it was stored?

[3-24]

A. Yes. This one has been mechanically treated in at least somewhat the same way that the other ones were, but it didn't crack.

Q. Now, sir, I'm going to hand you 8-F. Isn't this a higher density poly-plastic?

A. Yes.

Q. There's no cracking on this 8-F, is there?

A. No.

Q. It's not leaking, is it?

A. I don't believe so.

Q. So, if this thing sat in the storage room for six months properly stored and this thing, or number A at your feet sat in the storage room for six months, you're saying that that one leaked because of the way it was stored and this one didn't.

A. You use an adjective which I'm going to remind you of. You said that one was properly stored. If this one had been properly stored I think it wouldn't have leaked either.

Q. But that's a high density polyethylene, right?

A. Yes. It is also thicker in its wall.

Q. Right, and the Tussi container is a high density polyethylene, right?

A. Yes, they were.

Q. And sir, wouldn't a manufacturer who's done stability studies on its containers and who maybe this manufacturer hasn't had a recall in many years know better than you what Tussi should be stored in?

[3-25]

A. I never said what Tussi should be store in.

Q. Would ;you recommend to a pharmaceutical company that Tussi-Organadin should be stored in a milk jug or water jug?

A. Well, possibly.

Q. Aren't these things, these water jugs and milk jugs cheaper to manufacture?

A. Certainly.

Q. So, if these jugs were okay and they're cheaper to manufacture, wouldn't you assume that a pharmaceutical company would want to put their product in that container?

A. Not necessarily. I'm bothered by the train of the argument which suggests that this failure occurred while the material was in use by the pharmacist as opposed to having been stored subsequently to that. As far as I know, the failures occurred not when the material was being used, but subsequently.

Q. When it was stored?

A. Which means at least during its use it seemed to perform fine.

Q. What's the shelf life of Tussi?

A. I have no idea.

Q. And you really don't know a heck of a lot about Tussi-Organadin, do you?

[3-26]

A. No.

Q. Do you know what the term "paneling" is?

A. There are several uses of the term paneling in the plastics business which are not consistent with one another. The electronic people refer to paneling as discontinuous changes in thickness when you manufacture multi-layered circuit cords. The people in the

bottle industry refer to the collapse of sidewalls of bottles as being paneling. Which one are we talking about?

Q. Sir, I just asked you if you were acquainted with the term paneling.

A. I am.

Q. Thank you. Now, these milk jugs, these things are manufactured to hold milk and water, right?

A. That's correct.

Q. They're manufactured to contain aquous solutions, right?'

A. Yes.

Q. So they're not manufactured to hold Tussi cough syrup, are they?

A. Not specifically, no.

MR. STEITZ: I've nothing further, Judge.

THE COURT: Redirect examination.

REDIRECT EXAMINATION

BY MR. MARGULIS:

[3-54]

Margulis/Direct

lower than this, Lederles wanted our business of the high volume, so what the salesman would do is that we would be invoiced for this and then the salesman would bring in the numbers that you're seeing down here. The salesman would bring in product. Now, we talk about samples, it's important that everybody re-

alize that a sample is no different than any other product. It's only marked for a means of a different distribution. A sample is a product that's made under the same quality and the same products. It's just in a different manner of distribution. And they would bring in products to lower this price and those calculations that you will see on here and also on the others are that of the salesman bringing in merchandise to reduce these costs. We in turn reduce these costs to the people that we serviced.

Q. And is that what this zero over here means, that there was no charge?

A. No charge for the products, that's correct.

Q. And Exhibit U, we don't have to go through it, but does it illustrate the same type of transaction?

A. Yes. As a matter of fact, this is Mr. "Umers" computation of the monies that he owed us to bring in to reduce the price.

Q. So that the trading, this is one form of trading in samples?

A. That's correct.

Q. As long as I'm up here let me ask you to talk to us a little bit about an exhibit we have already seen and that's Exhibit L that Julie Hogan testified about.

[3-55]

Isn't it correct that sample trading, sample purchasing made up an infinitesimal small percentage of your business?

A. Yes, sir. As you can see we have the amount of purchases that we waived the drug purchases and the 22/100 of one percent —

Q. Of your total volume?

A. Of total volume. It was extremely — our volume, it was extremely —

Q. And in 1985 to '86, which was the last year that you were involved in the sample purchasing and trading, what was the figure?

A. It was 77/100 of one percent.

Q. And this is to the best of your knowledge accurate?

A. Yes, its is.

Q. Did you in fact discuss that table and chart with the accountant, Mr. Dino?

A. Yes. When we began to gather the data, I went to our accountant and I asked him to dig out all of our purchases and so forth and to give me the information to begin to do the calculations, and they helped us with this chart.

APPENDIX D

EIGHTH CIRCUIT COURT OF APPEALS

OPINION

UNITED STATES of America, Appellee,

v.

Leonard S. DINO, Appellant.

No. 89-2140EM.

United States Court of Appeals,
Eighth Circuit.

Submitted June 13, 1990.
Decided Nov. 14, 1990.

Defendant pharmacist was convicted in the United States District Court for the Eastern District of Missouri, Stephen Nathaniel Limbaugh, J., for offenses related to his purchasing sample prescription drugs and selling samples to customers, and he appealed. The Court of Appeals, Arnold, Circuit Judge, held that: (1) evidence supported finding fraudulent misrepresentation for profit; (2) evidence permitted finding receipt of misbranded and adulterated drugs with intent to defraud or mislead; and (3) defendant's consent to search of storage area located near pharmacy was not rendered involuntary because law enforcement agent did not inform defendant that he could refuse consent to search of that building, whose address was not included on search warrant.

Affirmed.

1. Criminal Law

On appeal from convictions, Court of Appeals reviews evidence presented to jury in light most favorable to government.

2. Post Office

Evidence supported finding fraudulent misrepresentation for profit by pharmacist who purchased sample prescription drugs and sold samples to customers who did not know they were buying drugs not meant for resale; selling "samples" to customers deprived drug manufacturer of profit it would have received if it products had been acquired through intended channels, and customers were denied basic safeguards which manufacturers took pains to provide because at least some of the drugs which pharmacist sold had unknown expiration and not lot or serial number with which to effect recall if necessary. 18 U.S.C.A. § 1341.

3. Post Office

Evidence supported finding use of mails in furtherance of pharmacist's scheme to purchase sample prescription drugs and sell samples to customers; former sales representative testified that two checks in payment for samples were mailed to his home, witness testified that notation on purchase order of samples which state check should be sent was in pharmacist's handwriting and identified another exhibit consisting of check and piece of paper bearing notation to send check that included sales representative's name and address, and envelope found at pharmacy that contained receipt totaling pharmacy's sample drug order from sales representative was introduced. 18 U.S.C.A. § 1341.

4. Drugs and Narcotics

Marketing of sample drugs is not per se misbranding. Federal Food, Drug, and Cosmetic Act, §§ 301(c), 303(b), 502(a, f), 21 U.S.C.A. §§ 331(c), 333(b), 352(a,f).

5. Drugs and Narcotics

Evidence permitted finding that defendant pharmacist received misbranded drugs with intent to defraud or mislead where pharmacist purchased sample prescription drugs and sold samples to customer and defendant pharmacist received bags of samples not marked with lot numbers, serial numbers, or expiration dates; definition of misbranded as including false or misleading labeling includes drugs received without lot numbers or expiration dates, as doctors, patients, and drug manufacturers all rely on pharmacists to sell safe and effective drugs, not drugs impossible to trace for recall, or which may have passed expiration date. Federal Food, Drug, and Cosmetic Act, §§ 301(c), 303(b), 502(a,f), 21 U.S.C.A. §§ 331(c), 333(b), 352(a,f).

6. Drugs and Narcotics

Evidence permitted finding that defendant pharmacist received adulterated drugs with intent to defraud or mislead, where defendant purchased sample prescription drugs and sold samples to customers; drug manufacturer's quality control director testified that jugs defendant used to store samples of cough syrup were intended only for short-term contact and doubted purity if cough syrup stored in jugs, which appeared to have collapsed inward during period before trial, as material used to construct jugs might have leaked into cough syrup and caused its adulteration. Federal Food, Drug, and Cosmetic Act, § 501, 21 U.S.C.A. § 351.

7. Searches and Seizures

Defendant's consent to search of storage area located near pharmacy was not rendered involuntary because law enforcement agent did not inform defendant that he could refuse consent to search of that building, whose address was not included on search warrant.

Arthur S. Margulis, St. Louis, Mo., for appellant.

James K. Steitz, St. Louis, Mo., for appellee.

Before ARNOLD and WOLLMAN, Circuit Judges, and FLOYD R. GIBSON, Senior Circuit Judge.

ARNOLD, Circuit Judge.

This appeal involves the criminal conviction of a St. Louis pharmacist for purchasing sample prescription drugs and selling the samples to customers. The defendant, Leonard S. Dino, admits purchasing samples from drug-company representatives from 1977 until 1986. Dino also admits using these samples to fill prescriptions ultimately purchased by his customers. Dino claims, however, that this was not an illegal practice until 1988, when Congress specifically outlawed purchasing and trading in sample drugs. Indeed, because no statute specifically barred the sale of drug samples for the years in question, the indictment charged Dino with mail fraud, conspiracy to defraud, and misbranding and adulteration of prescription drugs. Dino maintains that he is not guilty of these crimes. For reasons explained below, we affirm the judgment entered by the District Court.[1]

On September 3, 1986, law-enforcement agents executed a search warrant at Council Plaza Pharmacy in St. Louis, one of two pharmacies owned by ;the defendant. The agents seized various documents and containers of drugs as evidence in an ongoing investigation of the activities of certain drug salesmen. A seven-count criminal indictment followed, naming Dino and a former manager at Council Plaza, Joseph Greco. At Dino's trial, government witnesses included Dick Meyer, a former sales representative of Ross Laboratories, and Jerry Hayes, a sales representative of Wyeth Laboratories. Both testified that they

[1] The case was tried before the Honorable Stephen N. Limbaugh, United States District Judge for the Eastern and Western Districts of Missouri.

sold sample drugs to the defendant, in violation of their company's rules. The samples were sometimes delivered to Dino out of their original containers, with the "sample" marking removed by a razor or with rubbing alcohol. The Salesmen also testified that the samples sold to Dino often lacked the drugs' lot numbers, serial numbers, and expiration dates.

Other government witnesses included former employees of the defendant. They testified about, among other things, Dino's purchases of Tussi cough syrup samples from Bob Haller, a sales representative of Carter-Wallace, Inc. Some of the defendant's employees had seen samples of the cough syrup poured from their original bottles into larger containers. The jugs used to store the cough syrup did not bear lot numbers or expiration dates. The defendant, in turn, presented witnesses who claimed that selling sample drugs was a wide-spread practice in the pharmacy business until 1988. That was when Congress passed an amendment to the Federal Food, Drug, and Cosmetic Act of 1970 prohibiting the sale of drug samples. 21 U.S.C. § 333(b).

At the conclusion of the trial, the jury returned verdicts of guilty on five counts: using the mails to defraud drug manufacturers and drug customers, and to obtain money and property by fraud, in violation of 18 U.S.C. §§ 2 and 1341 (Counts I, II, and V); receiving and delivering adulterated and misbranded drugs, in violation of 21 U.S.C. §§ 331(c) and 333(b) (Count VII); and conspiracy to commit these offenses, in violation of 18 U.S.C. § 371 (Count VI). Dino was fined $10,000 on each of Counts I and II, and was sentenced to concurrent terms of twelve months' imprisonment, with 90 days to be served on work release and the remaining nine months suspended. The District Court suspended the imposition of sentence for Counts V, VI, and VII, and placed Dino on probation for five years.

On appeal, Dino argues that his actions were not fraud under the mail-fraud statute. Dino claims that the government failed to

prove that he had a specific intent to defraud drug manufacturers or customers, or to obtain money or property by fraud. State rules and regulations did not prohibit the practice during the years in question, Dino continues, and he stopped trading in samples in 1986 when it was brought to his attention that buying and selling samples might be wrong.

[1,2] We review the evidence presented to the jury in the light most favorable to the government. *United States v. Noibi,* 780 F.2d 1419, 1421 (8th Cir. 1986). The jury heard that Dino had purchased samples from several different drug representatives, over a period of years, at considerably less than the price charged for the drugs by the manufacturers. (A reasonable jury could readily understand that selling "sample" drugs to consumers deprives the drug manufacturer of the profit it would get if its products were acquired through the intended channels. Furthermore, customers did not know they were buying drugs not meant for resale. because at least some of the drugs Dino sold had an unknown expiration date, and no lot or serial number with which to effect a recall, if necessary, customers were denied basic safeguards which drug companies take some pains to provide. We think this is fraudulent misrepresentation for profit. (Although the defendant claims he kept this information in this computer, Dick Meyer testified that he gave Dino samples in plastic baggies and vials not bearing expiration dates or serial or lot numbers. Tr. 1:36.) Thus, we conclude that the government sufficiently proved a scheme "to defraud, or for obtaining money or property by means of false or fraudulent. . . representations. . . ." 18 U.S.C. § 1341.

[3] Dino also claims that the government presented insufficient evidence to prove use of the mails in furtherance of the scheme. We disagree. Dick Meyer testified that two checks in payment for samples were mailed to his home. Tr. 1:38-39. Kathleen Sharkey testified that a notation on a purchase order of samples, which read, "Send check after merchandise is checked in," was

in Dino's handwriting. Tr. 1:79. This evidence was offered to prove use of the mails in Count I. Meyer identified another exhibit, offered to prove a mailing for Count II, which was a check together with a piece of paper bearing the notation, "Julie, send check," and included Meyer's name and address. Tr. 1:40. Evidence offered to prove a mailing for Count V was an envelope postmarked April 7, 1986, found at Council Plaza Pharmacy. The envelope contained a receipt totaling the pharmacy's sample drug order from Bob Haller. Tr. 2:90-91. We think all of this evidence is more than sufficient to prove use of the mails within the meaning of 18 U.S.C. § 1341.

[4,5] Dino's third claim on appeal is that the government offered insufficient evidence to prove that he received misbranded and adulterated drugs with intent to defraud or mislead, prohibited by 21 U.S.C. §§ 331(c), 333(b). A drug is "misbranded" if, among other things, its labeling is "false or misleading in any particular," or if its labeling lacks "adequate warnings . . . against unsafe dosage or methods or duration of administration or application, in such ;manner and form, as are necessary for the protection of users. . . ." 21 U.S.C. § 352(a), (f). We agree that marketing of sample drugs is not *per se* misbranding. See *United States v. Various Articles of Drugs*, 332 F.2d 286, 287-88 (3d Cir. 1964). However, the government proved that Dino received bags of samples not marked with lot numbers, serial numbers, or expiration dates. Tr. 1:36, 2:8-9. While the statute does not specifically state that a drug in a container without this information is "misbranded," we think the language "false or misleading in any particular" includes drugs received without lot numbers or expiration dates. This is because doctors, patients, and drug manufacturers all rely on pharmacists to sell safe and effective drugs—not drugs impossible to trace for a recall, or which may have surpassed an expiration date. Based on the evidence, the jury was entitled to find that Dino could not have kept track of the expiration dates and lot numbers on the samples he bought.

[6] The question of adulteration is easier. 21 U.S.C. § 351(a)(2)(B) defines adulteration to include packaging a drug not in conformity with "current good manufacturing practice" to assure that the drug meets specified safety standards. The government presented the testimony of Dr. Ken Blessel, Director of Quality Control for Carter-Wallace. Dr. Blessel testified that the jugs Dino used to store samples of Tussi cough syrup were intended only for short-term contact, unlike the specially designed original containers. Tr. 2:26. He noted that these jugs appeared to have collapsed inward during the period before trial. Tr. 2:28. Dr. Blessel doubted the purity of the Tussi stored in the jugs because the material used to construct the jugs may have leaked into the product and caused its adulteration. Tr. 2:28-29. Thus, we think the government sufficiently proved a violation of 21 U.S.C. § 351.

[7] Dino's last claim is that the District Court should have suppressed evidence seized from a storage area located near his pharmacy because the search warrant did not include the address of that building. The Magistrate[2] found that Dino consented to the search. Dino argues that he assumed the warrant was valid for the other building because the agent said so. We disagree that he is therefore entitled to have the evidence found there suppressed. Dino was shown the warrant. Dino's consent to the search of the other building does not become involuntary because the agent did not inform him he could refuse.

The judgment entered by the District Court is affirmed.

---

[2] The Honorable William S. Bahn, United States Magistrate for the Eastern District of Missouri. The District Court adopted the Magistrate's Report and Recommendation. No. 88-112 CR (5) (E.D. Mo. November 23, 1988).

APPENDIX E

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No. 89-2140EM

United States of America,
Appellee,

v.

Leonard S. Dino,
Appellant.

Order Denying Petition for Rehearing
With Suggestion for Rehearing En Banc

Appellants' suggestion for rehearing en banc has been considered by the court and is denied by reason of the lack of a majority of the active judges voting to rehear the case en banc.

Petition for rehearing by the panel is also denied.

February 11, 1991

Order Entered at the Direction of the Court:

/s/ Robert D. St. Vrain
Clerk, U.S. Court of Appeals, Eighth Circuit

(2)

No. 90-1583

Supreme Court, U.S.
FILED
JUN 12 1991
OFFICE OF THE CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1990

LEONARD S. DINO, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

KENNETH W. STARR
Solicitor General

ROBERT S. MUELLER, III
Assistant Attorney General

SIDNEY M. GLAZER
Attorney
Department of Justice
Washington, D.C. 20530
(202) 514-2217

QUESTION PRESENTED

Whether petitioner's convictions for mail fraud and for receiving and distributing adulterated and misbranded drugs were supported by sufficient evidence.

TABLE OF CONTENTS

	Page
Opinion below	1
Jurisdiction	1
Statement	1
Argument	5
Conclusion	8

TABLE OF AUTHORITIES

Cases:

Berkemer v. *McCarty*, 468 U.S. 420 (1984)	6
Carpenter v. *United States*, 484 U.S. 19 (1987)	5
McNally v. *United States*, 483 U.S. 350 (1987)	5
United States v. *Articles of Drug*, 625 F.2d 665 (5th Cir. 1980)	7
United States v. *Lovasco*, 431 U.S. 783 (1977)	6

Statutes:

Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, § 4, 102 Stat. 96-98 (21 U.S.C. 353)	6
18 U.S.C. 371	2
18 U.S.C. 1341	2, 3
21 U.S.C. 331	7
21 U.S.C. 331(c)	2
21 U.S.C. 333(b)	2
21 U.S.C. 351	4
21 U.S.C. 351(a)(2)(B)	7
21 U.S.C. 352	4
21 U.S.C. 352(a)	7

In the Supreme Court of the United States

OCTOBER TERM, 1990

No. 90-1583

LEONARD S. DINO, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINION BELOW

The opinion of the court of appeals (Pet. App. A36-A43) is reported at 919 F.2d 72.

JURISDICTION

The judgment of the court of appeals was entered on November 14, 1990. A petition for rehearing was denied on February 11, 1991. The petition for a writ of certiorari was filed on April 15, 1991. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Following a jury trial in the United States District Court for the Eastern District of Missouri, petitioner was convicted on three counts of mail fraud,

in violation of 18 U.S.C. 1341; one count of receiving and delivering adulterated and misbranded drugs, in violation of 21 U.S.C. 331(c) and 333(b); and one count of conspiracy, in violation of 18 U.S.C. 371. He was sentenced to concurrent 12-month terms of imprisonment on two of the mail fraud counts, with 90 days to be served on work release and the remaining nine months suspended. He was also fined $10,000 on the mail fraud counts. The court suspended imposition of sentence on the remaining counts and placed petitioner on probation for five years. The court of appeals affirmed. Pet. App. A36-A43.

1. The evidence at trial showed that from 1977 until 1986, petitioner was the owner and operator of two pharmacies in the St. Louis, Missouri, area. During that time, he purchased sample prescription drugs from drug company representatives and used those samples to fill his customers' prescriptions. The pharmaceutical samples were often delivered to petitioner out of their original containers, without lot numbers, serial numbers, expiration dates, or "sample" markings. In some instances, the samples had been obtained by the salesmen in violation of company rules. Petitioner typically paid for his supplies by mailing checks directly to the salesmen. Pet. App. A39-A40; Gov't C.A. Br. 4-9.

The samples purchased by petitioner included a prescription cough syrup produced by Carter-Wallace, Inc. After petitioner bought the cough syrup samples, he or his employees typically poured the samples from their individual bottles into larger containers that did not bear either drug lot numbers or expiration dates. The pharmacy filled prescrip-

tions for the cough syrup from the large containers. Pet. App. A40; Gov't C.A. Br. 6.[1]

The director of quality control for Carter-Wallace testified that the bottles in which petitioner stored the cough syrup were designed to hold water-based products and were inappropriate for liquids like the cough syrup. The syrup, he explained, could have caused the bottles to collapse inward as the plastic from which they were made deteriorated. In fact, the bottles that petitioner used to store the cough syrup had begun to collapse in that manner. Although the quality control expert had not performed studies on petitioner's containers, he testified that in his opinion the deterioration of the bottles could cause plastic to leach into and adulterate the cough syrup stored inside. The expert stated that if Carter-Wallace were aware of such contamination, it would recall the entire batch of cough syrup. Pet. App. A17-A24, A43. An expert witness in clinical pharmacy testified that ingestion of plastic-contaminated cough syrup could cause kidney failure, decreased liver function, neurological toxicity, and paralysis. Those effects could also result if expired cough syrup were ingested. Gov't C.A. Br. 13.

2. The court of appeals affirmed. The court ruled that the evidence supported the existence of a fraudulent scheme under 18 U.S.C. 1341, because the jury could conclude that the purchase of inexpensive samples deprived their manufacturers of profits they would have earned had petitioner procured their products legitimately. Furthermore, petitioner's retail sale of samples, which were not intended for resale, denied consumers the benefits of various safety meas-

---

[1] The drug samples sold by petitioner also included birth-control pills and "Slow-K." Gov't C.A. Br. 5, 6.

ures such as lot numbers, which are used in case of a recall, and expiration dates, which ensure the drugs' efficacy. The court concluded that petitioner's scheme constituted fraudulent misrepresentation for profit. Pet. App. A39-A43.

The court also held that the drugs petitioner sold were misbranded under 21 U.S.C. 352, which prohibits labeling that is "false or misleading in any particular." Petitioner's drugs were falsely labeled, the court ruled, because they did not have lot numbers or expiration dates. The court explained that "doctors, patients, and drug manufacturers all rely on pharmacists to sell safe and effective drugs—not drugs impossible to trace for a recall, or which may have surpassed an expiration date." Pet. App. A42.

Finally, the court found that petitioner's drugs were adulterated within the meaning of 21 U.S.C. 351, since adulteration includes packaging that is not in conformity with "current good manufacturing practice." Petitioner's storage of the cough syrup in ordinary plastic bottles, and not in the manufacturer's specially designed containers, was not good practice because it jeopardized the purity of the drug. Thus, the drugs were adulterated. Pet. App. A43.[2]

---

[2] The court of appeals also rejected petitioner's claims that the evidence failed to prove use of the mails in furtherance of his scheme (Pet. App. A41-A42) and that the district court should have suppressed evidence (*id.* at A43). Petitioner has not raised those contentions in this Court.

ARGUMENT

Petitioner contends that the evidence was insufficient to sustain his conviction. First, he argues (Pet. 6-8) that the mail fraud counts must be reversed under *McNally* v. *United States*, 483 U.S. 350 (1987), because the evidence did not show that the manufacturer or petitioner's customers were defrauded. That argument is without merit.

McNally held that the mail fraud statute is limited to the protection of property rights and does not outlaw schemes to defraud citizens of the intangible right to good government. Thus, in *Carpenter* v. *United States*, 484 U.S. 19 (1987), this Court rejected the argument that a newspaper employee's disclosure of pre-publication information was not proscribed by the mail fraud statute. The Court explained that the mail and wire fraud statutes "reach any scheme to deprive another of money or property," and that the words "to defraud" include "wronging one in his property rights." *Id.* at 27.

In this case, the evidence showed that petitioner devised a scheme to defraud the pharmaceutical manufacturers of money and property. As the court of appeals noted (Pet. App. A41), petitioner bought his drugs from the sales representatives for considerably less than the price charged for the drugs by their manufacturers. The manufacturers were thus deprived of the profits they ordinarily would have made; *i.e.*, they were deprived of money and wronged in their property rights within the meaning of the mail fraud statute.[3] In addition, petitioner's custom-

[3] Petitioner does not argue that he did not deprive manufacturers of their profits, but contends (Pet. 7) that those potential profits were "minuscule." The court of appeals determined, however, that the lost profits were considerable (Pet.

ers were defrauded of basic safeguards when drugs of unkown expiration date and no lot or serial number were substituted for pharmaceuticals that were within their period of efficacy and were subject to recall if the need arose.[4]

Petitioner next argues (Pet. 8-11) that the government failed to prove that the drugs were adulterated or misbranded. He contends that the testimony of the government's expert witness was based upon an insufficient evidentiary foundation and that the evidence of adulteration was therefore inadequate. Because petitioner did not challenge the expert's testimony in the court of appeals (and apparently did not object to the expert's testimony at trial), he has waived that argument. See *Berkemer* v. *McCarty*, 468 U.S. 420, 443 (1984); *United States* v. *Lovasco*, 431 U.S. 783, 788-789 n.7 (1977). In any event, there is no merit to the point.

The government's expert examined the bottles that petitioner used to store the cough syrup and determined that they had begun to collapse inward. The

---

App. A41) and in any event the mail fraud statute does not require that a fraud exceed a dollar minimum. Moreover, the record indicates that petitioner paid the drug companies' salesmen for the drugs and not the manufacturers, so the manufacturers apparently obtained no return at all on some of the drugs that petitioner resold. See Gov't C.A. Br. 4-5, 7, 9, 41.

[4] Contrary to petitioner's contention, nothing in the enactment of the Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, § 4, 102 Stat. 96-98, with its provision restricting the sale of drug samples, 21 U.S.C. 353, absolved petitioner for his fraudulent acts. Schemes in violation of the mail fraud statute are no less criminal because Congress has subsequently addressed the particular fraudulent acts that constituted the scheme.

expert's opinion that the deterioration of the containers could cause toxins to be released into the cough syrup was therefore based on an adequate foundation. Moreover, petitioner's use of containers that were not designed to hold the cough syrup that he stored in them is itself an "adulteration" under the statute, which prohibits packaging a drug in a manner that does not conform with "current good manufacturing practice." 21 U.S.C. 351(a)(2)(B); see Pet. App. A43.

Even if the government's evidence of adulteration was insufficient, the government proved that the drugs were misbranded, which is sufficient to sustain the conviction under 21 U.S.C. 331, since the statute separately prohibits both adulteration and misbranding. The statute defines "misbranded," 21 U.S.C. 352(a), as "false or misleading in any particular," which, as the court of appeals held, includes drugs lacking the safeguards provided by expiration dates and lot numbers. The lot numbers make it possible for the manufacturers to recall defective drugs, and the expiration dates help avoid the risk of injuries of the sort described by the testimony of the clinical pharmacist. Without that information, neither the pharmacist nor the physician can protect the consumer; drugs lacking that information are thus misbranded.[5]

---

[5] Petitioner's reliance on *United States* v. *Articles of Drug*, 625 F.2d 665 (5th Cir. 1980), is misplaced. That case held that a doctor's prescription exempts a drug from many of the ordinary labeling requirements because the doctor would convey the necessary safety information to the patient. Nothing in that case leads to the conclusion that pharmaceutical products are properly sold when all evidence of their lot numbers and expiration dates has been erased; indeed, without those data the doctor (as well as the pharmacist and the pa-

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

KENNETH W. STARR
Solicitor General

ROBERT S. MUELLER, III
Assistant Attorney General

SIDNEY M. GLAZER
Attorney

JUNE 1991

---

tient) could not be sure that a particular lot of a drug was safe and effective.

☆ U. S. GOVERNMENT PRINTING OFFICE: 1991 282061 20589